ZENECA Pharmaceuticals
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SENT VIA UNITED PARCEL SERVICE

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
HFA No. A-305, Room No. 1061
Rockville, MD 20857

Dear Madam/Sir:

Re: Docket Number 99D-0296

Reference is made to the FDA draft guidance entitled "Guidance for Industry Formal Meetings With Sponsors and Applicants for PDUFA Products," which was published in the Federal Register on March 19, 1999.

Zeneca Pharmaceuticals has reviewed this draft document; our comments are provided below.

Section II. A. - We suggest including meetings held to resolve a "clinical hold" in the Type A meeting designation.

Section II. B. - We suggest including meetings to discuss the completion of regulatory obligations of drugs approved under Subpart H (CFR 314.510) in the Type B meeting designation. These important meetings seek agreement with the reviewing division that all of the requirements of the drug approved under CFR 314.510 no longer apply and that traditional approval may now be granted.

Section II. C. - We suggest clarification of the Type C meetings, not just "other than Type A or Type B" (for example: protocol development, review tool issue).

Section II. - The last paragraph of this sections states ". . ., if a meeting needs to be canceled or postponed by the Agency, the FDA component should reschedule the meeting in a timely manner." The phrase "timely manner" is too vague; therefore, we suggest FDA should not cancel a meeting without offering a reschedule date.

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Section III. 1. - We suggest adding the phrase "(if applicable)" after "Product name and application number."

Section IV. A. - We suggest including a disclaimer in the event that FDA should deem it necessary to schedule a meeting quickly for any reason; the number of days prior to the meeting that the information package needs to be submitted will be reduced.

Section IV. B.1. - We suggest adding the phrase "(if applicable)" after "Product name and application number."

Section VI. - We suggest including a statement specifically stating that only FDA's meeting minutes are considered the official minutes.

Section IV. - We suggest including a time frame for submission of sponsor draft minutes for consideration by the reviewing division during the preparation of the official minutes.

Please do not hesitate to contact me should you require clarification on any of the above comments.

Sincerely,

Sandra Bihary-Acquaviva

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SLB/DLB/jr

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